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REMARKS

The amendments to the claims do not add new matter. The amendment to claims 1, 11, 15, 20, and 23, which includes the limitation of a threaded surface throughout the elongated body of the presently claimed biomedical implant, is supported throughout the specification, including an illustration in Figure 2 and at page 2, lines 26-30 ("...another embodiment of the subject implant that has a **threaded outer surface**..."), [emphasis added in bold], and page 5, line 30- page 6, line 2 ("**thread profile** can range from about...") [emphasis added in bold]. The amendment to claims 2, 3, and 5 corrects for a punctuation error. The amendment to claims 4, 12, and 18 correct for a grammatical error. The amendment to claim 6 was required by the Patent Office to correct for an improper antecedent recitation. The amendment to claim 17, 18, 19 includes the recitation of "biomedical implant of claim 1" in the preamble and body of the claim, so as to properly recite prior antecedent basis. Independent claims 1, 11, 20 and 23, which have been amended to recite "a first end for engaging a driving and securing device and a second end for initially engaging adjacent vertebrae," is supported throughout the specification, including at page 5, lines 11-12 ("As shown in Figure 1, embodiment 200 discloses holes 205 for engaging a securing and driving device."); and at page 2, lines 11-12 ("implanting the subject implant into the intervertebral space in a spinal fusion procedure."). Independent claims 1, 11, 15, 20 and 23, which have been amended to recite that the elongated body comprises a continuously tapered and threaded surface "from about 5 mm to about 25 mm," is supported throughout the specification, including at page 5, lines 25-25 ("The length B can range from about 5 to about 25 mm. . ."). New claim 24 is supported by the embodiment shown in Fig. 10A and the discussion in the specification at page 9, line 10-23.

Therefore, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection

Claims 1-4, 9, and 17-23 are rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by U.S. Patent No. 6,277,149 (Boyle).

Claims 15 and 16 are rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by U.S. Patent No. 6,111,164 (Rainey).

Claims 5-8 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,111,164 (Rainey).

Claim 10 is rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,174,311 (Branch).

Claims 11-14 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,258,125 (Paul).

Claims 6 and 7 are rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite.

The Applicants will address each of these bases for rejection in Sections I-VI, respectively, which follow.

I. 35 U.S.C. § 102(e), U.S. Pat. 6,277,149 (Boyle)

Claims 1-4, 9, and 17-23 are rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by U.S. Patent No. 6,277,149 (Boyle). As amended herein, independent claim 1 is drawn to an implant comprising an elongated body with a continuously tapered and threaded surface beginning on or proximate to the first end of the elongated body, extending throughout the length of the elongated body, and ending on or proximate to the second end of the elongated body, wherein the implant is composed of cortical, cortico-cancellous, or cancellous bone. Also amended herein, claims 20 and 23 are drawn to a method of treating a spinal defect or injury and method for fusing vertebrae, respectively, using the implant of claim 1.

The Patent Office contends that Boyle discloses:

> a biomedical implant (10) designed for implantation into a spine of a patient comprising an elongated body (12) having first and second ends (FIG. 1), the elongated body being tapered such that tapering begins at a first position on or proximate to the first end and continues down the length of the elongated body down to a second position on or proximate to the second end; as best seen in FIGs. 1, 3, 9; wherein the implant is comprised of cortical or cancellous bone; as set forth in column 2, lines 40-45
>
> [Official Action, pages 2-3].

In order for a reference to anticipate a claim, the reference must teach every element of the claim. See *Verdegaal Bros. V. Union Oil Co. of California,* 2USPQ2d 1051,1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"); and MPEP §2131. To be anticipatory, Boyle must disclose each element and limitation of the claimed invention.

In the present case, Boyle fails to disclose the limitation of claims 1, 20, and 23 in which the implant comprises an elongated body **having continuously throughout a** tapered and **threaded surface**. Boyle discloses a ramp-shaped implant comprising "a series of **ridges formed over at least a portion**" of the upper and lower surfaces of the disclosed implant [column 2, lines 34-37, emphasis added in bold]. In contrast, the presently claimed implant comprises an elongated body that has a **threaded surface continuously throughout**. Those skilled in the art recognize that by the term "threaded" is meant a "**spiral**" or "**helical**" shape:

> **thread** - 4. the **spiral** or **helical** ridge of a screw, bolt, nut, etc.
>
> [Exhibit A: The American Heritage® Dictionary of the English Language Online, Fourth Edition, Copyright© 2000 by Houghton Mifflin Company.]

It is respectfully submitted that there is no **spiral or helical ridges** on the implants of Boyle. There are just **linear ridges** on **flat surfaces.** These linear ridges,

labeled as **28** in FIGS. 1, 3, 8, and 9, are described in Boyle as being positioned on the visually flat "upper" and "lower" surfaces:

> A series of **ridges 28** are positioned on at least a portion of upper and lower surfaces **22** and **24**. **Ridges 28** extend between side-walls **18** and **20**. The apex of each **ridge 28** defines a substantially right angle corner. **Ridges 28** are configured to engage the adjoining vertebrae and prevent the implant from backing out of a receiving bed formed between the adjoining vertebrae
>
> [Boyle at col. 4, lines 17-23, emphasis added in bold.]

For this reason, independent claims 1, 20, and 23, and dependent claims 2-4, 9, 17-19, 21 and 22, are not anticipated by Boyle. Therefore, withdrawal of this basis for rejection is respectfully requested.

II. 35 U.S.C. § 102(e), U.S. Pat. 6,111,164 (Rainey)

Claims 15 and 16 are rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by U.S. Patent No. 6,111,164 (Rainey). As amended herein, claim 15 is drawn to a method of producing a biomedical implant comprising an elongated body with a continuously tapered and threaded surface beginning on or proximate to the first end of the elongated body, extending throughout the length of the elongated body, and ending on or proximate to the second end of the elongated body, said method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block section from said bone at an angle substantially perpendicular to said ridge.

> The Patent Office contends that Rainey discloses:
>
> a method of producing a biomedical implant (10) that comprises an elongated body (12) having first and second ends (FIG. 1) wherein the first end comprises two or more oblique side (18), the method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block sections from the bone at an angle substantially perpendicular to the ridge; as best seen in FIGS. 2A-2C; and as set forth in column 2, lines 57-76 and column 3, lines 1-15 [Official Action at page 3].

In order for a reference to anticipate a claim, the reference must teach every element of the claim. See *Verdegaal Bros. V. Union Oil Co. of California,* 2USPQ2d 1051,1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"); and MPEP §2131. To be anticipatory, Rainey must disclose each element and limitation of the claimed invention.

In the present case, Rainey fails to disclose the limitation of claim 15 in which the implant comprises an elongated body **having continuously throughout a tapered and threaded surface**. Rainey discloses an implant comprising "one or more of circumferentially-located, transverse **grooves**" on the sidewall [column 2, lines 39-42, emphasis added in bold], instead of a **threaded** surface, as is presently claimed. Additionally, Figure 1C, for example, in Rainey illustrates that each of these grooves, labeled as element 28, are "**located on the side** of the dowel" embodiment [column 2, lines 42-53], and **does not extend continuously throughout**, as is presently claimed. Furthermore, Rainey discloses an implant having **parallel sidewalls**, instead of a **tapered** surface, as is presently claimed. Illustrated, for example, in Figure 1, the sidewalls, labeled as element 14, **extend at the same angle** throughout the length of the implant. In contrast, Applicants' presently claimed implant comprises an elongated body that has a **tapered** surface continuously extended throughout.

Therefore, independent claim 15 and claim 16, which is dependent therefrom, are not anticipated by Rainey. Applicants respectfully request withdrawal of this basis for rejection.

III. 35 U.S.C. § 103(a), U.S. Pats. 6,277,149 (Boyle) and 6,111,164 (Rainey)

Claims 5-8 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,111,164 (Rainey). Dependent claim 5 is drawn to the implant of claim 1, as amended herein, comprising an elongated body with a continuously tapered and threaded surface beginning on or proximate to the first end of the elongated body, extending throughout

the length of the elongated body, and ending on or proximate to the second end of the elongated body, wherein the implant is composed of cortical, cortico-cancellous, or cancellous bone, and wherein the first end is in the shape of a wedge. Claim 6, which is dependent upon claim 5, is drawn to the above implant wherein the wedge shape comprises two or more obliquely angled planar sections. Claim 7 is cancelled herein. Claim 8, which is dependent upon claim 1, further recites that the first end of the implant has two or more pinch cut outs formed thereon.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in the prior art. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. The Applicants respectfully submit that neither U.S. Patent No. 6,277,149 (Boyle) nor U.S. Patent No. 6,111,164 (Rainey), either individually or in combination, teaches or suggests the limitations of independent claim 1 and dependent claims 5, 6, and 8. In the present case, neither Boyle nor Rainey teach or suggest the limitation of claim 1 in which the implant comprises an elongated body **having continuously throughout a tapered and threaded surface.**

As discussed in Section I above, Boyle does not teach or suggest an implant comprising an elongated body **having continuously throughout a** tapered and **threaded surface**. Instead, Boyle teaches a ramp-shaped implant comprising "a series of **ridges** formed over at least **a portion**" of the upper and lower surfaces of the disclosed implant [column 2, lines 34-37, emphasis added in bold]. In addition, as discussed in Section II above, Rainey does not teach or suggest the limitation of claim 1 in which the implant comprises an elongated body having continuously throughout a **tapered and threaded** surface. Instead, Rainey teaches an implant comprising "one or more of circumferentially-located, transverse **grooves**" on the sidewall [column 2, lines 39-42, emphasis added in bold].

Therefore, neither Boyle nor Rainey, either individually or in combination, teach or suggest the "continuously tapered and threaded surface" limitation

of independent claim 1, or of claims 5, 6, and 8 which depend therefrom. Applicants respectfully request the withdrawal of this basis for rejection.

IV. 35 U.S.C. § 103(a), U.S. Pats. 6,277,149 (Boyle) and 6,174,311 (Branch)

Claims 10 is rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,174,311 (Branch). Dependent claim 10 is drawn to the implant of claim 1, as amended herein, comprising an elongated body with a continuously tapered and threaded surface beginning on or proximate to the first end of the elongated body, extending throughout the length of the elongated body, and ending on or proximate to the second end of the elongated body, wherein the implant is composed of cortical, cortico-cancellous, or cancellous bone, and wherein the first end of the implant defines a peg that is configured to engage a securing device.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in the prior art. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. The Applicants respectfully submit that neither U.S. Patent No. 6,277,149 (Boyle) nor U.S. Patent No. 6,174,311 (Branch), either individually or in combination, teaches or suggests the limitations of independent claim 1 and dependent claim 10.

The Patent Office admits that Boyle "did not teach of an implant having a peg portion in the first end to engage a securing device" [Office Action, page 4]. Additionally, the Patent Office states that Branch discloses "the use of peg portion for securely engaging a tool holder" [Office Action, page 4]. However, Applicants respectfully submit that neither Boyle nor Branch teach or suggest the limitation of claim 1 in which the implant comprises an elongated body **having continuously throughout a tapered and threaded surface.**

As discussed in Section I above, Boyle does not teach or suggest an implant comprising an elongated body having continuously throughout a tapered and threaded surface. Instead, Boyle teaches a ramp-shaped implant comprising "a series of **ridges** formed over at least a portion" of the upper and lower surfaces of the disclosed implant [column 2, lines 34-37, emphasis added in bold]. Moreover, Branch teaches tools for inserting implants that contain crescent, concave surfaces [abstract and column 3, lines 5-11]. Branch does not mention, teach, or even suggest any implant comprising an elongated body having continuously throughout a tapered and threaded surface.

Therefore, neither Boyle nor Branch, either individually or in combination, teach or suggest the "continuously tapered and threaded surface" limitation of independent claim 1, or of claim 10 which depend therefrom. Applicants respectfully request the withdrawal of this basis for rejection.

V. 35 U.S.C. § 103(a), U.S. Pats. 6,277,149 (Boyle) and 6,258,125 (Paul)

Claims 11-14 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,277,149 (Boyle) in view of U.S. Patent No. 6,258,125 (Paul). As amended herein, independent claim 11 is drawn to an implant, composed of two or more separate sections that can be joined together, that upon joining of the separate sections, comprises an elongated body with a **continuously tapered and threaded surface** beginning on or proximate to the first end of the elongated body, extending throughout the length of the elongated body, and ending on or proximate to the second end of the elongated body.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in the prior art. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. The Applicants respectfully submit that neither U.S. Patent No. 6,277,149 (Boyle) nor U.S. Patent No. 6,258,125 (Paul), either individually or in combination, teaches or suggests the limitations of independent claim 11 and dependent claim 12-14. In the present case, neither Boyle nor Paul, either individually or in

combination, teach or suggest the "**continuously tapered and threaded surface**" limitation of independent claim 11,

As discussed in Section I above, Boyle does not teach or suggest a multi-sectioned implant comprising an elongated body having continuously throughout a tapered and **threaded** surface. Instead, Boyle teaches a ramp-shaped implant comprising "a series of **ridges** formed over at least a portion" of the upper and lower surfaces of the disclosed implant [column 2, lines 34-37, emphasis added in bold]. Moreover, Paul does not teach or suggest a multi-sectioned implant comprising an elongated body having continuously throughout **a tapered and threaded** surface. Instead, Paul teaches an implant having a "**wedge-shaped profile** with a plurality of **teeth** located on top and bottom surfaces" [column 2, lines 15-18].

Therefore, neither Boyle nor Paul, either individually or in combination, teach or suggest the "continuously tapered and threaded surface" limitation of independent claim 11, or of claims 12-14 which depend therefrom. Applicants respectfully request the withdrawal of this basis for rejection.

VI. 35 U.S.C. § 112, Second Paragraph

Claims 6 and 7 are rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Patent Office stated that the term "said wedge shape" in claims 6 and 7 lack prior antecedent [Office Action, page 2].

Applicants have amended claim 6 to be dependent upon claim 5, which properly recites the term "a wedge shape". Applicants have cancelled claim 7 herein, thereby rendering the rejection moot.

In light of the amendment, Applicants respectfully submit that this basis for rejection is rendered moot. Applicants respectfully request the withdrawal of this basis for rejection.

CONCLUSION

Claims 1-23 stand rejected. Claim 7 is cancelled herein. Claim 24 has been added. Accordingly, claims 1-6 and 8-24 are pending.

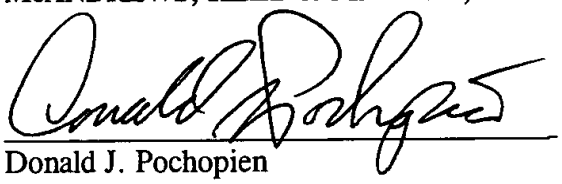
In view of the amendments and arguments provided herein, all bases for rejection of claims 1-4, 9, 15, 16, and 17-23 under 35 U.S.C. § 102(e) for alleged anticipation have been rebutted. In view of the amendments and arguments provided herein, all bases for rejecting claims 5-8, 10, and 11-14 under 35 U.S.C. § 103(a) have been rebutted or rendered moot. In view of the amendments provided herein, all bases for rejection of claims 6 and 7 have been rendered moot.

Applicants kindly note to the Patent Office that color photographs and/or drawings were not submitted in the present application. The drawings submitted in this application were in black and white.

Claims 1-6 and 8-24 are in condition for allowance.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

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thread [P] **Pronunciation Key** (thrĕd)
n.

1.
   a. Fine cord of a fibrous material, such as cotton or flax, made of two or more filaments twisted together and used in needlework and the weaving of cloth.
   b. A piece of such cord.
2.
   a. A thin strand, cord, or filament of natural or manufactured material.
   b. Something that suggests the fineness or thinness of such a strand, cord, or filament: *a thread of smoke.*
   c. Something that suggests the continuousness of such a strand, cord, or filament: *lost the thread of his argument.*
3. A helical or spiral ridge on a screw, nut, or bolt.
4. *Computer Science.*
   a. A portion of a program that can run independently of and concurrently with other portions of the program.
   b. A set of posts on a newsgroup, composed of an initial post about a topic and all responses to it.
5. **threads** *Slang.* Clothes.

h c efe e ce c e ch h e e

v. **thread·ed, thread·ing, threads**
v. tr.

a. To pass one end of a thread through the eye of (a needle, for example).
b. To pass (something) through in the manner of a thread: *thread the wire through the opening.*
c. To pass a tape or film into or through (a device): *thread a film projector.*
d. To pass (a tape or film) into or through a device.

2. To connect by running a thread through; string: *thread beads.*
3.
   a. To make one's way cautiously through: *threading dark alleys.*
   b. To make (one's way) cautiously through something.
4. To occur here and there throughout; pervade: "More than 90 geologic faults thread the Los Angeles area" (Science News).
5. To machine a thread on (a screw, nut, or bolt).

v. intr.

1. To make one's way cautiously: *threaded through the shoals and sandbars.*
2. To proceed by a winding course.
3. To form a thread when dropped from a spoon, as boiling sugar syrup.

[Middle English, from Old English thrǣd. See ter-[1] in Indo-European Roots.]

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thread'er *n.*

threaded

Thread \Thread\, v. t. [imp. & p. p. Threaded; p. pr. & vb. n. Threading.] 1. To pass a thread through the eye of; as, to thread a needle.

2. To pass or pierce through as a narrow way; also, to effect or make, as one's way, through or between obstacles; to thrid.

Heavy trading ships . . . threading the Bosphorus. -- Mitford.

They would not thread the gates. --Shak.

3. To form a thread, or spiral rib, on or in; as, to thread a screw or nut.

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threaded

thread

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